

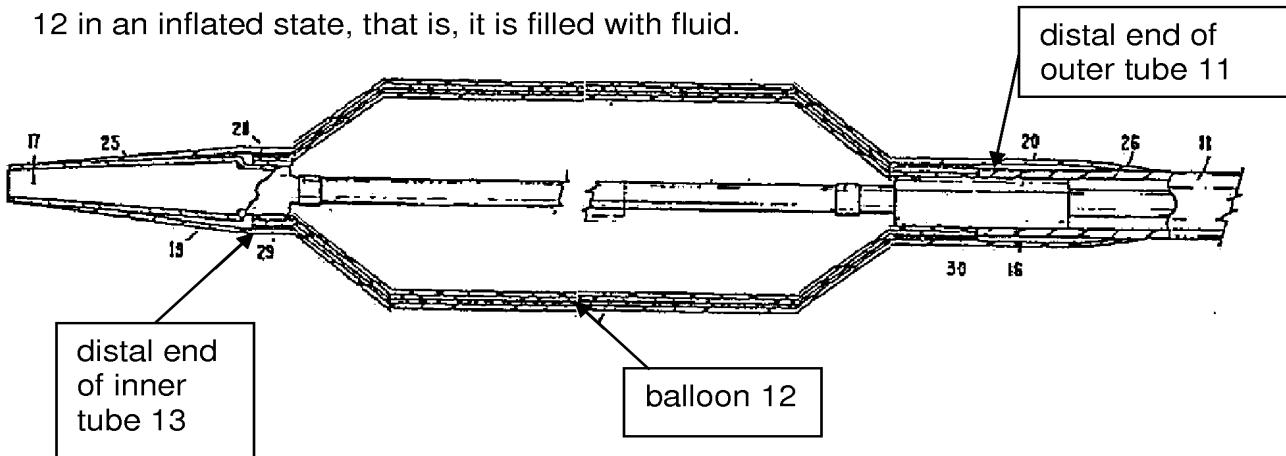
## REMARKS

The Office Action of September 15, 2010, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

In the above Office Action, claims 1-21 were rejected under 35 U.S.C. § 103(a) as being anticipated by *Cook* (U.S. Patent No. 4,637,396) in view of *Fina* (U.S. Patent No. 4,911,163). For at least the following reasons, Applicants respectfully traverse these rejections.

The primary reference relied upon by the Examiner, *Cook*, is directed to a balloon catheter 10 including a catheter tube 11 and a flexible inner member 13. A balloon 12 is disposed coaxially about the inner member 13. Further, the proximal end of the balloon 12 is fixed and sealed to the distal end 16 of the catheter tube 11 and the distal end of the balloon 12 is fixed and sealed to the distal end 18 of the inner member 13. *Cook* thus discloses a balloon catheter which is a single catheter, i.e., the inner member 13 of *Cook*'s catheter is fixed to the outer tube 11 through the balloon.

A modified version of Fig. 2 of *Cook* is set forth below to illustrate the balloon 12 in an inflated state, that is, it is filled with fluid.



As shown in the above drawing, the balloon 12 is fixed between the distal portion of the inner tube 13 and the distal portion of the outer tube 11. If the outer tube 11 and the inner tube 13 are not fixedly secured to each other, the expanding medium (i.e. fluid) in the balloon would leak out. Accordingly, *Cook* does not disclose or suggest that "an inner surface of said outer catheter and an outer surface of said inner catheter are not fixedly secured to one another such that said inner catheter is removable from said outer catheter when said outer catheter hub and said inner catheter hub are disengaged from each other," as recited above in amended Claim 1.

The Examiner relies upon the balloon 12, having a three layer wall 22, 23, 24, as allegedly corresponding to the outer catheter of the claimed invention. Claim 1 of the present application comprises an outer catheter hub attached to a proximal end of the outer catheter body. In contrast, the proximal end of the balloon 12 is attached to the outer tube 11 as clearly shown in Fig. 2 -- not a hub 46 as the Examiner contends. As such, this interpretation of *Cook* does not meet all the recitations of Claim 1. Alternatively, if the outer tube 11 in *Cook* is alleged to correspond to the claimed outer catheter, this feature may be satisfied, but the distal end of the outer tube 11 is positioned at the proximal end of the balloon 12 such that a distance between the distal end 16 of the outer tube 11 and the distal end 18 of the inner tube 13 is defined by the length of the balloon 12 and is thus far more than the 10 mm recited in Claim 1. In either instance, all the features of Claim 1 are not met by *Cook*.

*Fina*, the secondary reference upon which the Examiner relies, discloses an assembly of an inner balloon catheter 1 and an outer balloon catheter 7. The inner

balloon catheter including the first balloon 2 protrudes from the distal end 12 of the outer balloon catheter 7, as clearly shown in Fig. 2. Therefore, the distance between the distal end of the inner balloon catheter 1 and the distal end of the outer balloon catheter 7 is over 10 mm. As such, *Fina*, fails to suggest the teaching found to be lacking in the primary reference to *Cook*. The Examiner's comments "draw applicants attention to fig 2 of Fina," as set forth on Page 7, line 8, however, the figure accompanying the Office Action appears to be Fig. 2 of *Cook*, which for the reasons explained above, does not meet this recitation.

In addition, the Examiner maintains that the catheters of *Cook* are capable of being disengaged and removed from one another. Applicants respectfully submit that while such destruction of *Cook* may be possible, it is certainly not suggested by *Cook*. *Cook* is intended to function as a sealed unit having a pressure seal at the joints 46 and 53 (Col. 4, lines 11-14) noted by the Examiner. Removal of the cap 46 as suggested by the Examiner would break the intended seal. As cautioned by the Federal Circuit, where a modification of the prior art device would render such device inoperable for its intended purpose, the mere fact that the prior art device could be so modified would not have made the modification obvious. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984). As such, Applicants respectfully submit that disengagement of the tubes of *Cook* would not be an obvious modification.

Moreover, there is inadequate evidence to support the Office Action's conclusion of obviousness, particularly taking into account the Patent Office's Examination Guidelines for Determining Obviousness Under 35 U.S.C. §103(a) in view of KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). The Guidelines state that the Examiner should clearly articulate why the claimed

invention would have been obvious. For example, the Supreme Court in KSR held that the Examiner "must [provide] some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, at 1396. The Supreme Court noted that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art." Id. To establish obviousness, it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." Id. In this case, it is not at all apparent why one would have been led to the stated modification since to do so would lead to the intended functionality of *Cook*. Simply because something could have been modified and a person of ordinary skill was capable of making the modification does not mean it would have been obvious to do so. Therefore, there is inadequate evidence supporting the conclusion that it would have been obvious to modify *Cook* in a manner as taught by *Fina* to arrive at the claimed invention.

Accordingly, Applicants submit that there is no suggestion to modify *Cook* in view of *Fina* as set forth by the Examiner.

Moreover, in *Cook*, the maximum outer diameter of the tip of the inner tube 13 (with the attached plastic tip 19) is larger than the inner diameter of the outer tube 11 (see, Fig. 2). Therefore, even if the catheter assembly were disengaged as proposed by the Examiner, the inner tube 13 could not be removed from the outer tube 11. Claim 21 defines the intended proximal removal of the inner tube from the outer tube which can not be accomplished even if *Cook* is taken apart as proposed by the Examiner.

The dependent claims define additional distinguishing aspects associated with the claimed invention. Since these dependent claims depend from an allowable independent claim, a detailed discussion of the additional distinguishing features recited in these dependent claims is not set forth at this time.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: /WLWeinstein/  
Wendi L. Weinstein  
Registration No. 34456

**Customer No. 21839**  
703 836 6620